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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,840	01/28/2002	Patrick Soon-Shiong	ABI1550-1	7072

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EXAMINER	
DELACROIX MUIRHEI, CYBILLE	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 06/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,840	SOON-SHIONG ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2005 and 11 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.0.05

Detailed Action

The following is responsive to the request for continued examination received March 16, 2005 and the amendment received Feb. 11, 2005.

Claims 1-5 and 7-21 are currently pending.

All previous claim rejections set maintained in the office action mailed Nov. 17, 2004 are withdrawn in view of applicant's amendment and the remarks contained therein.

New Ground(s) of Rejection

Claim Rejection(s)—35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-5, 7-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation "about" in these claims is a relative term, which renders the claims indefinite. The expression "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of closeness or proximity, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

"The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear

measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all of the criteria for patentability and whether the specification meets the criteria of 35 USC 112, first paragraph with respect to the claimed invention." Please see MPEP 2173.

Because the limitation "about" would invite subjective interpretations, the Examiner respectfully submits that the public would not be informed of the boundaries of what constitutes infringement of the present claims and thus the claims do not meet the requirements of 35 USC 112, second paragraph.

Claim Rejection(s)—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1-5, 7-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 9406422 ('422) (already of record).

WO '422 discloses a method of administering for a long term, low doses of paclitaxel to a patient suffering from cancer (breast, lymphoma). The method specifically requires administering as a 96-hour continuous infusion a dose level of paclitaxel containing between 70 and 140 mg/M^2. The paclitaxel solution is delivered through a permanent central intravenous catheter, with cycles repeated every 21 days. WO '422 additionally teaches that the administration of low dose paclitaxel results in less adverse side effects and reduces the chance of a patient developing mdr paclitaxel resistance. Please see the abstract; page 5, lines 1-24; page 7, lines 4-26; page 9, lines 3-6.

WO '422 also discloses a composition comprising a final infusion solution prepared by diluting the total daily paclitaxel dose in 250 or 500 ml of 5% dextrose injection, USP or 0.9% sodium chloride injection USP in a glass, polyolefin or polypropylene container. Please see page 7, lines 4-9.

WO '422 does not specifically disclose that the sub-therapeutic dose is in the range of about 1% up to about 20% of the conventionally administered amount.

However, since WO '422 discloses that low doses of paclitaxel results in fewer adverse side effects and reduces the chance of developing mdr paclitaxel resistance, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the method of WO '422 such that the resulting amount is effective to maintain efficacy in the treatment of the cancer while reducing unwanted adverse side effects and development of mdr resistance. Furthermore, the court has held "it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 105 USPQ 233, 235 (CCPA 1955). Only if "the results of optimizing a variable are 'unexpectedly good' can a patent be obtained for a claimed critical range." In re Antonie, 195 USPQ 6, 8 (CCPA 1977). See also In re Geisler, 43 USPQ2d 1362 (CAFC 1997). Therefore, the Examiner respectfully submits, absent evidence of unexpected results, it would have been prima facie obviousness to arrive at the claimed dosage range.

Additionally, WO '422 does not disclose local administration of paclitaxel, nor does WO '422 teach the claimed length of treatment. However, one of ordinary skill in the art would reasonably expect local administration to be effective in delivering paclitaxel to the tumor or cancer to be treated. Moreover, since the length of treatment is related to the efficacy of the overall treatment, it would have been obvious to one of ordinary skill in the ad at the time the invention was made to further modify the length of treatment in WO '422 such that therapeutic levels of paclitaxel are achieved without the undesirable side effects.

Conclusion

The art made of record and not relied upon is considered pertinent to applicant's disclosure. Fargnoli et al., US 2004/0143004.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 31, 2005
CDM

Cybille Delacroix-Muirheid
Patent Examiner Group 1600